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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,655	02/01/2002	Bruno Giannetti	054756-5003-00	1818
28977	7590	07/02/2004	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			ROBERT, EDUARDO C	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/061,655	GIANNETTI ET AL.	
	Examiner	Art Unit	
	Eduardo C. Robert	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I (claims 1-13), in the reply filed on May 12, 2004 is acknowledged.

It is noted that applicants canceled claims 14-16 directed to Invention II and present new claims 17-24. The introduction of new claims 17-24 provoke a new restriction between the claims 1-13 and the new claims 17-24 as follow:

- I. Claims 1-13, drawn to a method for the effective treatment of articulating joint surface cartilage, classified in class 623, subclass 23.63.
- III. Claims 17-24, drawn to a cartilage repair structure, classified in class 623, subclass 11.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practice with a different apparatus, e.g. an structure having a matrix with no hyaluronic acid or that is not cell-free.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group III, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the response filed on May 12, 2004, applicants foresaw the potential for a new restriction between the claims 1-13 and new claims 17-24 (see applicant's response filed on May 12, 2004, page 5) and further **elected the new claims 17-24 for prosecution**. It is noted that the election will be treated as an **election without traverse** since the election of new claims 17-24 on page 5 of applicant's remarks of the response filed on May 12, 2004 does not appear to traverse the potential restriction which applicant clearly foresaw.

Claims 1-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on May 12, 2004.

The requirement is therefore made FINAL.

Priority

It is noted that the application data sheet, filed on February 01, 2002, states that the application is a "continuation" of pending PCT application PCT/IB00/01093. However, the

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declaration, filed on April 23, 2002, states that the application only claims "Foreign" priority and not priority under 35 U.S.C. 120. Thus, it is unclear what type of priority applicants want to claim. It is noted that the examiner will use the information of the "application data sheet" as the correct information for examination purposes until applicants clarify this issue.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the World Intellectual Property Organization (PCT/IB00/01093) on August 2, 2000. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (U.S. Patent 5,769,899).

Schwartz et al. disclose an structure comprising a porous bio-absorbable matrix made from hyaluronic acid. It is noted that hyaluronic acid is inherently cell-free. The matrix has an overlaid of chondrocyte cells (see col. 7, lines 4-30). The cells are clearly somehow held on the matrix in order to permit vascular invasion.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (U.S. Patent 5,769,899).

Schwartz et al. disclose the claimed invention except for the chondrocyte cells being autologous (claim 19), or allogenic (claim 20), or xenogenic (claim 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the structure of Schwartz et al. with the chondrocyte cells being autologous, or allogenic, or xenogenic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

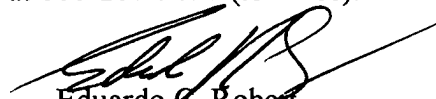
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333.

The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.